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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,513	03/29/2004	Stacie Canan-Koch	PC19150A	1955

28940 7590 02/14/2006

AGOURON PHARMACEUTICALS, INC.
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EXAMINER	
LEWIS, AMY A	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 02/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/811,513	CANAN-KOCH ET AL.	
	Examiner	Art Unit	
	Amy A. Lewis	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 November 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7* is/are pending in the application.

4a) Of the above claim(s) *8-12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☒ Claim(s) *4-6* is/are objected to.

8)☒ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/12/04 & 6/28/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Case

The Amendment, filed 3 August 2004, has been entered into the application. Accordingly, the specification has been amended to include continuity data.

Priority to US Provisional Application No. 60/459,433, filed 3/31/2003, is acknowledged.

Claims 1-7, as filed 29 March 2004, are presented for examination.

Response to Restriction/Election Requirement

Applicant's election *with traverse* of Group II (claims 4-7) in the reply filed 3 August 2004 is acknowledged. In addition, based upon due reconsideration, Group I (claims 1-3) and Group II (claims 4-7) have been rejoined.

Claims 8-12 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected subject matter, there being no allowable generic or linking claim.

The remaining Groups drawn to various processes of use are not rejoined at present. The restriction is maintained for the reasons of record as set forth in the Office Action (Restriction Requirement, dated 4 November 2005): the remaining groups demonstrate alternate processes of use and are drawn to unrelated and dissimilar method that require separate searches in the literature and raise different issues of patentability.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of

the allowable product claim will be rejoined in accordance with the provisions of M.P.E.P. § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 C.F.R. 1.116; amendments submitted after allowance are governed by 37 C.F.R. 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 C.F.R. 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35U.S.C. §§101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to maintain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Claim Objections

Claims 4-6 objected to because of the following informalities: the terms "irenotecan" and "temozolamide" are misspelled and should be corrected to read ---irinotecan--- and ---temozolomide--- (emphasis added). Appropriate correction is required.

Double Patenting

Statutory Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

1) Claim 1 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 4 of prior U.S. Patent No. 6495541. This is a double patenting rejection.

Nonstatutory Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2) Claim 1 is rejected on the ground of nonstatutory double patenting over claims 1-3, and 5 of U. S. Patent No. 6495541 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is ~~fully disclosed~~recited in claim 1 of the '541 patent. ~~and is covered by the patent since t~~The patent and the application are claiming common subject matter, as follows: both the instant application and US Patent No. 6495541 are drawn to pharmaceutical compositions of 8-fluro-2-(4-methylaminomethyl-phenyl-phenyl)-1,3,4,5-tetrahydroazepino[5,4,3-cd]indol-6-one. The currently claimed compound/composition is the obvius product of the process of making the compound/composition,

~~Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.~~

3) Claims 1-3 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6495541. Although the conflicting

claims are not identical, they are not patentably distinct from each other because they are both drawn to pharmaceutical compositions of 8-fluro-2-(4-methylaminomethyl-phenyl-phenyl)-1,3,4,5-tetrahydroazepino[5,4,3-cd]indol-6-one. Regarding the oral and injectable formulations, it is obvious to make a pharmaceutical composition in a form suitable for administration to a patient.

4) Claims 1-7 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6495541, in view of Zeldis et al. (US Patent Application Publication No. US 2002/0035090; published on 21 March 2002).

Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both drawn to pharmaceutical compositions of 8-fluro-2-(4-methylaminomethyl-phenyl-phenyl)-1,3,4,5-tetrahydroazepino[5,4,3-cd]indol-6-one.

U.S. Patent No. 6495541 does not teach dacarbazine.

Zeldis et al. teaches the anticancer agents irinotecan, temozolomide, and dacarbazine (see p. 8-9). The reference also teaches the use of the anti-cancer drugs in combination with another agent for improving the tolerance of patients to chemotherapy and radiation treatment. The reference also teaches treatment of various specific cancer, including prostate and colorectal. (See: p. 4, [0033-0035]; Examples 1 and 4).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to make the phosphate salt of 8-fluro-2-(4-methylaminomethyl-phenyl-phenyl)-1,3,4,5-tetrahydroazepino[5,4,3-cd]indol-6-one and the chemotherapeutic agent dacarbazine in a pharmaceutical composition. The skilled artisan would have been motivated to combine the two agents, having been taught by the prior art (Weber) that 8-fluro-2-(4-

methylaminomethyl-phenyl-phenyl)-1,3,4,5-tetrahydroazepino[5,4,3-cd]indol-6-one is known to be used in combination with other cytotoxic agents and that dacarbazine is a known anticancer agent used in combination with other agents. The person of ordinary skill in the art would have had a reasonable expectation of success in making such a combination, having been taught by the prior art that both agents are useful in treating cancer and that both agents are known to be used in combination therapy regimens.

5) Claim 1 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6977298. Although the conflicting claims are not identical, they are not patentably distinct from each other because a method of preparing a compound renders the compound itself obvious. Therefore, instant claim 1 is an obvious variation of claims 1-8 of U.S. Patent No. 6977298.

Nonstatutory Double Patenting--Provisional:

6) Claims 1-3 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 5- 7, and 12 of copending Application Serial No. 11/233835 (Liu, Jai et al.). Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim a phosphate salt of 8-fluro-2-(4-methylaminomethyl-phenyl-phenyl)-1,3,4,5-tetrahydroazepino[5,4,3-cd]indol-6-one. Regarding instant claim 2, drawn to an oral dosage form, it would have been obvious to a person of ordinary skill in the art to make an oral pharmaceutical composition for administration to a patient,

motivated by the ease of administration. Therefore the instant claims are an obvious variation of the copending 11/233835 claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7) Claims 1-3 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 of copending Patent Application Publication No. 2006/0009517 (Application Serial No. 11/221245; Weber et al.).

Although the conflicting claims are not identical, they are not patentably distinct from each other because 2006/0009517 teaches a compound of formula (I) which meets the limitations of 8-fluro-2-(4-methylaminomethyl-phenyl-phenyl)-1,3,4,5-tetrahydroazepino[5,4,3-cd]indol-6-one, as instantly claimed. The claims are not patentably distinct from each other because a method of using a compound renders the compound itself obvious. Therefore the instant claims are an obvious variation of the copending Patent Application Publication No. 2006/0009517 claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8) Claims 1-7 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 of copending Patent Application Publication No. 2006/0009517 (Application Serial No. 11/221245; Weber et al.), in view of

Zeldis et al. (US Patent Application Publication No. US 2002/0035090; published on 21 March 2002).

Although the conflicting claims are not identical, they are not patentably distinct from each other because 2006/0009517 teaches a compound of formula (I) which meets the limitations of 8-fluro-2-(4-methylaminomethyl-phenyl-phenyl)-1,3,4,5-tetrahydroazepino[5,4,3-cd]indol-6-one, as instantly claimed. In addition, claim 8 of copending 2006/0009517 claims a method potentiating the cytotoxicity of a cytoxic drug, comprising administering a compound of formula (I), in combination with the cytotoxic drug.

Patent Application Publication No. 2006/0009517 does not claim the specific drugs irinotecan, temozolomide, and dacarbazine to be used in the pharmaceutical combination.

Zeldis et al. teaches the anticancer agents irinotecan, temozolomide, and dacarbazine (see p. 8-9). The reference also teaches the use of the anti-cancer drugs in combination with another agent for improving the tolerance of patients to chemotherapy and radiation treatment. The reference also teaches treatment of various specific cancer, including prostate and colorectal. (See: p. 4, [0033-0035]; Examples 1 and 4).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to make the phosphate salt of 8-fluro-2-(4-methylaminomethyl-phenyl-phenyl)-1,3,4,5-tetrahydroazepino[5,4,3-cd]indol-6-one and the chemotherapeutic agent dacarbazine in a pharmaceutical composition. The skilled artisan would have been motivated to combine the two agents, having been taught by the prior art (Weber) that 8-fluro-2-(4-methylaminomethyl-phenyl-phenyl)-1,3,4,5-tetrahydroazepino[5,4,3-cd]indol-6-one is known to be used in combination with other cytotoxic agents and that irinotecan, temozolomide, and

dacarbazine are known anticancer agent used in combination with other agents. The person of ordinary skill in the art would have had a reasonable expectation of success in making such a combination, having been taught by the prior art that both agents are useful in treating cancer and that both agents are known to be used in combination therapy regimens.

The claims are not patentably distinct from each other because a method of using a compound renders the compound itself obvious. Therefore the instant claims are an obvious variation of the copending Patent Application Publication No. 2006/0009517 claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9) Claims 1-6 are rejected under 35 U.S.C. 102(a) as being anticipated by Webber et al. (US Patent No. 6495541).

Webber et al. '541 teaches a poly (ADP-ribosyl) transferase (PARP) inhibitor in the treatment of various diseases, including various cancers (see abstract). Webber et al. teaches the phosphate salt of 8-fluro-2-(4-methylaminomethyl-phenyl-phenyl)-1,3,4,5-tetrahydroazepino[5,4,3-cd]indol-6-one in a pharmaceutical composition (See: claims 1-4 and claim 4 in particular; col. 9 lines 8 and 13). The reference also teaches the compounds in combination with cytotoxic agents and/or radiation; the reference teaches the specific cytotoxic agents irinotecan (of instant claims 4 and 5) and temozolamide (of instant claims 4 and 6) as instantly claimed (see: abstract; col. 3, lines 18-20).

10) Claims 1-6 are rejected under 35 U.S.C. 102(e) as being anticipated by Webber et al. (US Patent No. 6977298, with a priority date of 10 January 2000). US Patent No. 6977298 is considered an equivalent teaching to US Patent No. 6495541.

Webber et al. '298 teaches a poly (ADP-ribosyl) transferase (PARP) inhibitor in the treatment of various diseases, including various cancers (see abstract). Webber et al. teaches the phosphate salt of 8-fluro-2-(4-methylaminomethyl-phenyl-phenyl)-1,3,4,5-tetrahydroazepino[5,4,3-cd]indol-6-one in a pharmaceutical composition (See: claims 1-8; col. 79 Example IIII; col. 9 lines 8 and 13). The reference also teaches the compounds in combination with cytotoxic agents and/or radiation; the reference teaches the specific cytotoxic agents irinotecan (of instant claims 4 and 5) and temozolamide (of instant claims 4 and 6) as instantly claimed (see: abstract; col. 3, lines 18-20).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11) Claims 1-7 are rejected under 35 U.S.C. 103(a) as being obvious over US Patent No. 6495541 (Webber et al.), in view of Zeldis et al. (US Patent Application Publication No. US 2002/0035090; published on 21 March 2002).

Webber et al. teaches a poly (ADP-ribosyl) transferase (PARP) inhibitor in the treatment of various diseases, including various cancers (see abstract). Webber et al. teaches the phosphate salt of 8-fluro-2-(4-methylaminomethyl-phenyl-phenyl)-1,3,4,5-tetrahydroazepino[5,4,3-cd]indol-6-one in a pharmaceutical composition (See: claims 1-4 and claim 4 in particular; col. 9 lines 8 and 13). The reference also teaches the compounds in combination with cytotoxic agents and/or radiation; the reference teaches the specific cytotoxic agents irinotecan (of instant claims 4 and 5) and temozolamide (of instant claims 4 and 6) as instantly claimed (see: abstract; col. 3, lines 18-20). Weber also teaches oral and parenteral (i.e. injection) administration (see: col. 25).

Weber does not teach the chemotherapeutic agent dacarbazine.

Zeldis et al. teaches the anticancer agents irinotecan, temozolomide, and dacarbazine (see p. 8-9). The reference also teaches the use of the anti-cancer drugs in combination with another agent for improving the tolerance of patients to chemotherapy and radiation treatment. The reference also teaches treatment of various specific cancer, including prostate and colorectal. (See: p. 4, [0033-0035]; Examples 1 and 4).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to make the phosphate salt of 8-fluro-2-(4-methylaminomethyl-phenyl-phenyl)-1,3,4,5-tetrahydroazepino[5,4,3-cd]indol-6-one and the chemotherapeutic agent dacarbazine in a pharmaceutical composition. The skilled artisan would have been motivated to combine the two agents, having been taught by the prior art (Weber) that 8-fluro-2-(4-

methylaminomethyl-phenyl-phenyl)-1,3,4,5-tetrahydroazepino[5,4,3-cd]indol-6-one is known to be used in combination with other cytotoxic agents and that dacarbazine is a known anticancer agent used in combination with other agents. The person of ordinary skill in the art would have had a reasonable expectation of success in making such a combination, having been taught by the prior art that both agents are useful in treating cancer and that both agents are known to be used in combination therapy regimens.

In addition, the following case law is believed to be relevant to the instant claim rejections:

> *In re Kerkhoven* (205 USPQ 1069, CCPA 1980) states that "It is *prima facia* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the same purpose: the idea of combining them flows logically from their having been individually taught in the prior art." Therefore, it would have been obvious to a person of ordinary skill in the are at the time the invention was made to combine 8-fluro-2-(4-methylaminomethyl-phenyl-phenyl)-1,3,4,5-tetrahydroazepino[5,4,3-cd]indol-6-one and dacarbazine, motivated by their having been taught by the prior art to be useful in treating various specific cancers, consonant with the reasoning of the cited case law.

The applied reference (US Patent No. 6495541) has a common assignee and inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by

another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Pertinent Art:

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- Burton E and Prados M. "New Chemotherapy options for the treatment of malignant gliomas," 1999 *Current Opinion in Oncology* 11(3): 157-. The reference teaches the cytotoxic chemotherapeutic agents dacarbazine, temozolomide, and irinotecan.

- Calabrese CR, et al. "Anticancer chemosensitization and radiosensitization by the novel poly(ADP-ribose) polymerase-1 inhibitor AG14361," 2004 *J Natl Cancer Inst* 96: 56-67. The reference teaches the poly(ADP-ribose) polymerase-1 inhibitor AG14361 in combination with temozolomide and irinotecan.

- Helleday et al. (US Patent Application Publication No. US 2005/0143370) teaches the compound 8-fluro-2-(4-methylaminomethyl-phenyl-phenyl)-1,3,4,5-tetrahydroazepino[5,4,3-cd]indol-6-one in pharmaceutical composition. See claims 1 and 4.

- Pullen, RH, et al. "Chiral separation retention mechanisms in high-performance liquid chromatography using bare silica....," 1997 *J of Chromatography* 691: 187-193 (Provided by applicant on PTO form 1449). The reference discloses the

compounds DU 124884 and KC 9048, which are similar to the claim compound, but missing the fluorine.

- Miknyoczki SJ, et al., "Chemopotentiation of temozolomide, irinotecan, and cisplatin activity by CEP-8600, a poly(ADP-ribose) polymerase inhibitor," April 2003 *Molecular Cancer Therapeutics* 2: 371-382. The reference teaches a different poly(ADP-ribose) polymerase inhibitor in combination with temozolomide and irinotecan (the instantly claimed second agents) for chemopotentiation.

Conclusion

Claims 1-7 are rejected. No claims are allowed.

Contact Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy A. Lewis whose telephone number is (571) 272-2765. The examiner can normally be reached on Monday-Friday, 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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